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Tralieve 50 mg/ml solution for injection for dogs

Authorised

- Tramadol hydrochloride

Product identification

Medicine name:
Tralieve 50 mg/ml solution for injection for dogs

Active substance:
Tramadol hydrochloride

Target species:
Dog

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
Tramadol hydrochloride
50.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02AX02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Norway

Available in:
Norway

Package description:
Multi-pack with 10 boxes each containing 1 vial of 10 ml
Multi-pack with 6 boxes each containing 1 vial of 10 ml
Multi-pack with 10 boxes each containing 1 vial of 50 ml
Multi-pack with 10 boxes each containing 1 vial of 20 ml
Box with 1 vial of 50 ml
Box with 1 vial of 20 ml
Box with 1 vial of 10 ml
Multi-pack with 6 boxes each containing 1 vial of 50 ml
Multi-pack with 6 boxes each containing 1 vial of 20 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Dechra Regulatory B.V.

Marketing authorisation date:
11/12/2017

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
16-11478

Date of authorisation status change:
2/01/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0226/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

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Package Leaflet

This document does not exist in this language (English). You can find it in another language below.